Research Proposal Form of the Thesis Entitled

COMPARATIVE EVALUATION OF RADICULAR SECTIONAL MICROCRACKS FORMATION DURING ROOT CANAL PREPARATION USING DIFFERENT ROTARY FILE SYSTEMS: *AN INVITRO STUDY*

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By

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Introduction:

The success of endodontic treatment depends upon thorough chemo-mechanical canal preparation by preserving the course of the canal, cleaning, and eliminating bacterial infection of the entire root canal system. Residual tissue, bacteria, or debris can contribute to endodontic failure[1]. While striving for comprehensive biomechanical preparation of the canal, there is a risk of unintentionally damaging the root dentin. Such damage can create pathways for dentinal cracks, fine intricate fractures, or craze lines, and may even lead to vertical root fractures, ultimately causing treatment failure.[2] Complications such as transportation, ledge formation, and perforation are well documented during root canal preparation.[3]

Vertical root fracture represents a significant complication that can arise from root canal therapy, often leading to considerable frustration, resulting in tooth extraction [4]. Yoldas et al, [5] stated that root fracture can happen when a craze line spreads due to repeated stress from biting forces.[5] There are various factors like: excessive tissue loss during root canal preparation, dehydration of dentin, excessive root curvature, the positioning of prosthetic implants and various methods of sealing.[6]

Stainless steel hand file were first introduced by Kerr company, in the 1900s for biomechanical preparation. They are still widely used for their good tactile sensation, controlled instrumentation, and reduction in excessive removal of dentin. Dentists may encounter complications such as the development of ledges and canal transportation as a result of rigidity and reduced flexibility.[7]

To overcome shortcomings of stainless-steel file system, a series of hand reamers and hand files made from nickel titanium (Ni-Ti) were introduced in 1960 by William Bueller in Silver Springs, Maryland at the United States Naval Ordinance Laboratory. Its super elastic nature of Ni-Ti files, permits its easy placement in curved canals with less lateral force exertion. Inspite of these advantages, hand instrumentation with NiTi files were time consuming, this led to development of Ni-Ti files based on rotary motion. Many healthcare professionals, favor these systems for their benefits, including saving time and enhanced cutting efficiency.[9]

Rotary Ni-Ti instruments produce significant forces on root dentin during instrumentation that can lead to apical root micro- cracks reducing the long-term prognosis for teeth that have received endodontic treatment..[8,20] Additionally, Kim et al, [22] have found a potential relationship between the design and variable tapers of rotary Ni-Ti instruments and concluded that file design and its variable taper affects apical stress and strain concentrations during root canal instrumentation causing vertical root fractures.

There are ample of rotary filesystems available commercially but most economical and commonly used file system this day is Neoendo Flex, (Orikam Healthcare India Private Limited) a third-generation gold thermal-treated NiTi rotary file that has a triangular cross-section featuring precise cutting edges and a safety tip designed to prevent cutting. Another file system known for its flexibility and controlled memory technology is Hyflex CM (Coltene Whaledent, Altstetten, Switzerland) which has symmetrical cross-sectional design with 3 cutting edges. Another comparable economic file used commonly is Flexer (Mothercare International) with triangular cross section and self adapative technology.

There are no studies done till now for comparing this commonly and economical used rotary files for causing microcracks. Hence, the present study is based on comparison and evaluation of microcracks formation at different levels of root dentin occurring due to most economical and commonly used rotary file system.

Review of Literature:

- **Kesim B, Sagsen B et al(2017)**[11] compared the incidence of root cracks after root canal instrumentation with thermomechanical processed nickel-titanium (NiTi) files with different instrumentation kinematics. They horizontally sectioned all the teeth at 6mm level and examined through a stereomicroscope to determine the presence of dentinal microcracks. The findings indicated that the ProTaper Next and TF Adaptive instruments resulted in a considerably higher number of cracks compared to the hand files, RECIPROC, and K3XF. Additionally, no significant differences were observed between the experimental groups and the control group at the 6-mm level. Considering the constraints of this in vitro study, it was determined that all thermally treated Ni-Ti instruments and hand files induced microcracks in the dentin of root canals.
- **Nishad SV, Shivamurthy GB(2018)** [12] conducted study to compare the incidence of apical root crack formation after root canal preparation at different instrumentation lengths using ProTaper Universal (PTU), ProTaper Next (PTN) and ProTaper Gold (PTG) file systems. They selected eighty-four mandibular first premolars with single and straight roots, mounted on a resin block and exposed 1-2 mm of root apex was sectioned. Control groups were left unprepared, experimental groups were instrumented up to root canal length (RCL) and (RCL-1 mm) respectively using PTU, PTN and PTG. Root apices were then stained and stereomicroscopic images were obtained for evaluating apical root cracks. The data were analyzed using Chi-square, and Cramer test. The significance level was set at $P < 0.05$.

Results of the study showed significantly less dentinal defects between PTG and PTU while there was no significant difference between PTU-PTN and PTN-PTG. Thus, the conclusion was that PTG produced fewest number of cracks was observed in PTN and PTU.

- **Jaob J, Paul M et al (2019)[13]** conducted a study to identify cracks in root canal dentin after root canal instrumentation with hand K-Flex files, ProTaper Next, and self-adjusting engine-driven files. Ninety-two human mandibular first molars were randomly split into four groups, each with 23 teeth, based on the instrumentation method: group I had unprepared teeth (control), and group II used hand K-Flex files.(Sybron Endo); group III-ProTaper Next X1 and X2 (Dentsply Maillefer); group IV-self-adjusting file (ReDent Nova, Israel). All the roots were sectioned at 9 mm, 6 mm, and 3 mm from the apex and samples, were then subjected to a stereomicroscopic examination for detection of dentinal cracks. Statistical analyses were done using the Chi-square test with SPSS (version 19), and p value was set at $p < 0.05$. Results showed statistical significant differences between the instrumented groups. No dentinal cracks were found in the unprepared roots and those prepared with hand K-Flex files (0/23). Self-adjustingfile-instrumented group showed significantly less incidence of crack formation when compared to the ProTaper Next group with $p = 0.001$.
- **Bal, S. S., Pare, S., et al. (2020)[14]** conducted a study to compare the extent of dentinal microcracks in the radicular dentin in mandibular insicors and were divided into 4 groups:Hand K file system ,Group 2-XP-endo Shaper ,Groups 3-Neoendoflex file and Group 4-Hero Shaper files .Samples were sectioned 3, 6, and 9 mm from the apex, using a diamond disc. The samples were then observed through a scanning electron microscope at x50 enlargement. The study showed XP-endo Shaper group showed significantly less number of cracks than the Neo endo flex, and Hero Shaper groups. Hence, it was concluded that all the system, except hand K files, produced remarkable dentinal microcracks. The canals instrumented with the XP-endo Shaper exhibited the fewest cracks.
- **Guha, A., et.al(2020)[15]**. Conducted study to evaluate dentinal crack formation after root canal preparation with Neoendo flex and Mani silk files. 36 extracted single-rooted premolars were selected and randomly assigned to three groups, The root canal preparation was conducted for three groups: Hand K-file, Mani Silk, and Neoendo Flex files. Following this, the specimens were horizontally sectioned at distances of 3, 6, and 9 mm from the apex. The sectioned samples were examined under a stereomicroscope to assess the presence or absence of dentinal cracks. The data were analyzed using one-way ANOVA and the Chi-square test.

The findings indicated that Hand K-files and Mani Silk files resulted in fewer cracks compared to Neoendo Flex files; however, the differences among the three file groups at the 3 mm and 6 mm measurements were not statistically significant (P > 0.05).

- **Miguéns-Vila, R., Martín-Biedma,et al(2021)**[16]studied the influence of rotary (ProTaper Next [PTN; Dentsply Maillefer, Ballaigues, Switzerland] and ProTaper Gold [PTG, Dentsply Maillefer]) and reciprocating (WaveOne Gold [WOG, Dentsply Maillefer]) systems in dentinal microcrack generation after the preparation of curved root canals using micro-computed tomographic analysis.24 teeth were selected and evaluated and were scanned in a micro-computed tomographic device using an isotropic resolution of 6.78 μm and randomly assigned into 1 of 3 experimental groups according to the root canal instrumentation system used (PTN, PTG, or WOG).Pre- and postoperative cross-sectional images of the roots were examined to identify the presence of dentinal microcracks. Results showed overall, 26% of the images presented dentinal defects (n = 9188). Dentinal microcracks were observed in 24.6%, 26%, and 27.4% of the post-instrumentation images from the PTN, PTG, and WOG groups, respectively. Hence, this study concluded that root canal preparation with PTN, PTG, and WOG systems did not induce the formation of new dentinal microcracks.
- **Barakat, R. M., et al (2022)**[17]This study was carried out to assess the use of micro-CT analysis and the dentinal microcrack formation after retreatment of bioceramic sealer with adjunct laser-activated and ultrasonic-activated irrigation. Thirty human single-canal teeth (n = 30) that had been obturated with a bioceramic sealer using the single-cone technique were retreated utilizing NiTi rotary files. The samples were categorized into three equal groups: group 1 served as the control group and received no treatment; group 2 underwent ultrasonic activation of the irrigants and group 3 involved active irrigation with a diode laser operating at a wavelength of 980 nm. Micro-CT scans were conducted on the teeth before and following the retreatment protocols. Two observers viewed the cross-sectional images and calculated the number of dentinal defects. The occurrence of any cracks or craze lines on both the external and internal surfaces of the root was recorded. The data were evaluated utilizing Friedman's two-way analysis of variance alongside Fisher's exact test. A statistical significance threshold was established at $p < 0.05$. Nevertheless, the application of ultrasonic or laser-activated irrigation did not lead to a statistically significant rise in the number of cracks ($p = 0.345$).NiTi rotary root canal retreatment was associated with a significant increase in dentinal microcracks.

- **Bilaiya, S., Patni, et al(2022)**[18]A study was conducted to assess the development of dentinal microcracks in human mandibular molars by utilizing four distinct minimally invasive file systems at distances of 3, 6, and 9 mm from the apex, employing a stereomicroscope for observation. The study included 125 mesial roots of mandibular molars and were randomly divided into 5 groups and instrumented (n=25). Group 1 consisted of the Control Group (CG), while Group 2 was designated as the Self Adjusting File (SAF). Group 3 was identified as the XP-Endoshaper (XP), Group 4 as TRUShape (TS), and Group 5 as V Taper 2H (VT). Two operators evaluated each specimen for the occurrence of dentinal defects. A statistical analysis comparing the file systems was conducted using the Chi-square test, with a significance level set at $p<0.05$. The study's findings indicated that the VT file system demonstrated a higher incidence of microcracks at 25%. However, this was not statistically significantly greater than the rates observed in the XP (12%), TRUShape (12%), and SAF (4%) endodontic file systems. Thus, the conclusion was all file systems used in our research are minimally invasive files and produced few dentinal microcracks. VT files produced the largest number, while SAF led to the least micro-cracks.
- **Priyadarshni, P., Nagpal, A., et al(2023)**[19] study aims to compare the cracks produced by TruNatomy, Neoendo Flex, and Neoendo Neohybrid files during root canal preparation.Four groups of 25 samples each were considered. Using TruNatomy, Neoendo Flex, and Neoendo, Neohybrid files, or leaving the teeth unprepared (control), the teeth were subjected to root canal preparation. Horizontal sections were taken and stereomicroscopic evaluation was done. A chi-square tests were performed on the data. Results showed TruNatomy files created rare cracks compared to Neoendo Flex and Neoendo Neohybrid files.

Research Problem:

Root canal preparation using rotary file systems is a common practice in endodontics. Still, it can lead to the formation of radicular sectional microcracks, which might compromise tooth integrity and long-term success. However, the extent and nature of microcrack formation associated with different commonly used rotary file systems are not well-documented or compared.

Significance/ Importance:

Vertical root fractures are type of longitudinal tooth fractures if occurs, during or after root canal treatment, it causes painful experience for the patient and embarrassing for the dentist. This affects the survival rate of the tooth. Important Causes of longitudinal tooth fracture, (especially vertical root fractures) while or after root canal treatment can be misdiagnosed due to existing known cracks or craze lines produced while cleaning and shaping procedures. Various factors are associated with this type of dentinal cracks which can occur due to cleaning and shaping procedures which may include high concentration of sodium hypochlorite solutions, different root canal shaping techniques and instruments with variable cutting blades, taper and tip configuration, and also compaction techniques during root canal filling. Numerous studies has been done that link the use of rotary Ni-Ti files with dentinal defects. A potential correlation of Ni-Ti rotary instruments and the incidence of root fractures was identified by Kim et al. They concluded that the configuration of the file influences strain concentration and apical stress during the root canal instrumentation process.[14] Based on this background, this study aims on evaluate of dentinal cracks formation during biomechanical preparation with certain commonly used rotary files which may lead to fracture and painful conditions for the patient at later stages and can be helpful in saving the tooth from fracture and extraction.

Research Objectives:

1) To evaluate the presence or absence, propagation site and the number of dentinal microcracks developed using Hand K file.
2) To evaluate the presence or absence, propagation site and the number of dentinal microcracks developed using the Rotary Neo-Endo Flex file system.
3) To evaluate the presence or absence, propagation site and the number of dentinal microcracks developed using the Rotary SuperEndo Blue file system.
4) To evaluate the presence or absence, propagation site and the number of dentinalmicrocracks developed using the Rotary Hyflex CM File system.
5) To compare which file system shows minimum dentinal microcracks during root canal preparation.

Methodology:

Study design: This is an in-vitro study which will be undertaken on human extracted teeth, Samples will be collected from the Oral and maxillofacial surgery Department (KSD). Teeth scheduled for extractions due to periodontal diseases will be selected and the study will be undertaken at the Department of Conservative & Endodontics, karnavati School of dentistry, Gandhinagar.

Inclusion criteria:

Non-carious mandibular incisors.

Completely formed tooth apices

Single rooted teeth with single canal

Absence of any root caries

Exclusion criteria:

Carious teeth

Fractured teeth

Restored teeth

Open apices

Root resorption

Multiple canals

Calcified canals

Curved roots

Developmental anomaly or anatomical irregularities

All selected samples will be examined radiographically (bucco-lingually as well as mesiodistally) to rule out straight, single canals, and will be decoronated to standardize the length of the root. Samples will also be examined under dental operating microscope at 10x magnification to exclude the teeth with cracks or fracture lines. All the teeth were randomly divided into 5 groups :

Group 1: Control Group
Group II : Hand File
Group III: Neo-Endo flex file
Group IV: Super-Endo blue file
Group V: Hyflex-CM

Access opening and biomechanical preparation of all samples with their respective file systems were done as per manufacturer 's instructions with specific torque and speed. All the root samples will be then sectioned horizontally at 3mm,6mm and 9mm levels from the apices. The microcracks formed by biomechanical preparation will be examined under a stereomicroscope with 40x magnification. The evaluation will be done by a particular scoring criteria which will be :

Score 0: No defect

Score I: A line that extends from the external surface into the dentin, yet does not penetrate to the canal lumen.

Score II: A line that originates from the canal lumen and extends into the dentin, without making contact with the external surface.

Score III: A line that extends from the canal lumen and reaches the external surface.

Data Analysis:

Data will be analyzed by using Statistical Package for Social Sciences (SPSS) for Windows, Version 26.0. Chicago. Data will be entered in Microsoft Excel spread sheet and would be subjected to statistical analysis. . Kolmogorov-Smirnov test or Shapiro-Wilk test will be used to check the normality of the data. Data is categorical and it will be subjected to non parametric Chi-square test. Cramer's V will be used to check the strength of association between variables. P value with a 95% confidence interval will be set at 0.05 to indicate significance.

Ethical approval:

It is an in vitro study, which will be carried out on extracted tooth of the patients whose teeth might have been extracted due to periodontal reasons.

Sample size and Sampling method:

Sample size will be determined based on the results of pilot study by using G power software.

Expected outcome: This study will give insight into which economical and commonly used out of four rotary file systems should be taken into consideration for root canal preparations and will help clinicians avoid vertical root fractures-like situations that can lead to extraction. To our knowledge, no research has compared these three commonly used rotary file systems for microcracks detection till date.

References:

1. Eriksen, H.M., Kirkevang, L., & Petersson, K. (2002). *Endodontic Epidemiology and treatment outcome: General considerations. Endodontic Topics, 2*, 1-9.
2. Peters O. A. (2004). Current challenges and concepts in the preparation of root canal systems: a review. *Journal of endodontics*, *30*(8), 559–567. https://doi.org/10.1097/01.don.0000129039.59003.9d.
3. Pettiette MT, Metzger Z, Phillips C, Trope M (1999). Endodontic complications of root canal therapy performed by dental students with stainlesssteel K-files and nickel-titanium hand files. J Endod 25,230–4.
4. Tsesis I, Rosen E, Tamse A, Taschieri S, Kfir A(2010). Diagnosis of vertical root fractures in endodontically treated teeth based on clinical and radiographic indices: a systematic review. J Endod 36,1455–8.
5. Yoldas O, Gokhan A, Kuden C, Kasan Z (2012). Dentinal Microcrack Formation during Root Canal Preparations by Different NiTi Rotary Instruments and the Self-Adjusting File. J Endod 38,232-35.
6. Shemesh, H., Bier, C. A., Wu, M. K., Tanomaru-Filho, M., & Wesselink, P. R. (2009). The effects of canal preparation and filling on the incidence of dentinal defects. *International endodontic journal*, *42*(3), 208–213.
7. Walton R. E. (1976). Histologic evaluation of different methods of enlarging the pulp canal space. *Journal of endodontics*, *2*(10), 304–311.
8. Bier, C. A., Shemesh, H., Tanomaru-Filho, M., Wesselink, P. R., & Wu, M. K. (2009). The ability of different nickel-titanium rotary instruments to induce dentinal damage during canal preparation. *Journal of endodontics*, *35*(2), 236–238.
9. Vaudt J, Bitter K, Neumann K, Kielbassa AM (2009). Ex vivo study on root canal instrumentation of two rotary nickel-titanium systems in comparison to stainless steel hand instruments. IEJ 42,22–33.
10. Kim HC, Lee MH, Yum J, Versluis A, Lee CJ, Kim BM (2010). Potential relationship between design of nickel-titanium rotary instruments and vertical rootfracture.

11. Kesim, B., Sagsen, B., & Aslan, T. (2017). Evaluation of dentinal defects during root canal preparation using thermomechanically processed nickel-titanium files. *European journal of dentistry*, *11*(2), 157–161.

12. Nishad, S. V., & Shivamurthy, G. B. (2018). Comparative Analysis of Apical Root Crack Propagation after Root Canal Preparation at Different Instrumentation Lengths Using ProTaper Universal, ProTaper Next and ProTaper Gold Rotary Files: An *In vitro* Study. *Contemporary clinical dentistry*, *9*(Suppl 1), S34–S38.

13. Jacob J, Paul M, Sara B, Steaphen P, Philip N, Mathew J (2019) Comparative Analysis of Dentinal Crack Formation Following Root Canal Instrumentation with Hand K-Flex Files, ProTaper Next, and Self-adjusting Files. J Contemp Dent Pract.

14. Bal, S. S., Pare, S., Unnikrishnan, A., Shetty, D., Kumar, H. G., & Ragher, M. (2020). Detection of Dentinal Microcracks in Radicular Dentin after Shaping with XP-endo Shaper, Neoendo Flex Files, and Hero Shaper Using Scanning Electron Microscope: An *In Vitro* Study. *Journal of pharmacy & bioallied sciences*, *12*(Suppl 1), S259–S263.

15. Guha, A., Pandharikar, R., Shivangi, S., Rao, R. D., Verma, M., & Jain, A. K. (2020). Comparative evaluation of dentinal crack formation after root canal preparation with Neoendo Flex and Mani Silk files: An *in vitro* study. *Journal of conservative dentistry : JCD*, *23*(5), 468–472.

16. Miguéns-Vila, R., Martín-Biedma, B., De-Deus, G., Belladonna, F. G., Peña-López, A., & Castelo-Baz, P. (2021). Micro-computed Tomographic Evaluation of Dentinal Microcracks after Preparation of Curved Root Canals with ProTaper Gold, WaveOne Gold, and ProTaper Next Instruments. *Journal of endodontics*, *47*(2), 309–314.

17. Barakat, R. M., Almohareb, R. A., Alsayyar, A., Almalki, F., & Alharbi, H. (2022). Evaluation of Dentinal Microcracks following Diode Laser- and Ultrasonic-Activated Removal of Bioceramic Material during Root Canal Retreatment. *Scanning*, *2022*, 6319743.

18. Bilaiya, S., Patni, P. M., Jain, P., Raghuwanshi, S., Pandey, S. H., & Harinkhere,

C. (2022). Radicular dentinal microcracks during biomechanical root canal preparation using four minimally invasive endodontic files. *Medicine and pharmacy reports*, *95*(4), 455–460.

19. Priyadarshni, P., Nagpal, A., Arif, A., Sharma, A., Rahman, M., & Sinha, S. (2023). Comparative Evaluation of Dentinal Crack After Root Canal Preparation Using TruNatomy, Neoendo Flex, and Neoendo Neohybrid Files: An In Vitro Study. *Cureus*, *15*(11), e49593.
20. Mariyam, R., Khurana, N. S., Mann, J. S., Sidhu, H. S., A, S., & Mohan, M. (2024). Comparative Evaluation of the Incidence of Dentin Microcracks Following Biomechanical Preparation Using Four Different Nickel-Titanium Rotary File Systems: An In Vitro Study. *Cureus*, *16*(2), e53506.

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